

**UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

NYCOMED GmbH and WYETH,)
Plaintiffs,) Civil Action No. 1:08-00827 (RAG)
v.)
APOTEX INC. and APOTEX CORP.,) Magistrate Judge Nan R. Nolan
Defendants.) **Filed Electronically**
)

**REPLY TO APOTEX INC.'S
ANSWER AND COUNTERCLAIMS**

Plaintiffs Nycomed GmbH and Wyeth (collectively, "Plaintiffs") hereby reply to the Counterclaims of Apotex Inc. ("Apotex"), dated April 1, 2008, for which every allegation not expressly admitted is denied.

To the extent any of paragraphs 1-25 of Apotex's Answer are determined in whole or in part to state counterclaims or the basis for counterclaims, Plaintiffs incorporate by reference paragraphs 1-25 of their Complaint, and deny each and every additional averment contrary to the averments in Plaintiffs' Complaint contained in Apotex's paragraphs 1-25.

To the extent any of Apotex's denials and affirmative defenses are determined to state counterclaims, each and every one of the averments therein is denied.

The Parties

1. Apotex Inc. is a corporation incorporated and existing under the laws of Canada with a place of business in Ontario, Canada.

Answer: Plaintiffs are without sufficient knowledge to either admit or deny the allegations of paragraph 1 of the Counterclaims and therefore deny the allegations.

2. Nycomed GmbH purports to be a corporation incorporated and existing under the laws of Germany, having its principal place of business at Byk-Gulden-Str. 2, 78467 Konstanz, Germany.

Answer: Admitted.

3. Wyeth purports to be a Delaware corporation with offices at Five Giralda Farms, Madison, NJ 07940.

Answer: Admitted.

Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”) (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

Answer: The allegations contained in paragraph 4 of the Counterclaims constitute a legal conclusion to which no response is required. To the extent that paragraph 4 of the Counterclaims is deemed to state factual allegations or mixed allegations of law and fact, Plaintiffs deny the allegations of paragraph 4 of the Counterclaims.

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

Answer: Plaintiffs admit that Apotex in paragraph 5 of the Counterclaims purports to claim jurisdiction under various sections of Title 28 of the United States Code. The remaining

allegations contained in paragraph 5 of the Counterclaims constitute a legal conclusion to which no response is required. To the extent that paragraph 4 of the Counterclaims is deemed to state factual allegations or mixed allegations of law and fact, Plaintiffs deny the allegations of paragraph 4 of the Counterclaims.

6. This Court has personal jurisdiction over Plaintiffs because Plaintiffs have availed themselves of the rights and privileges of this forum by suing Apotex Inc. in this District, and because Plaintiffs conduct substantial business in, and have regular and systematic contacts with, this District.

Answer: Plaintiffs' admit that for the purpose of this litigation only, this Court has personal jurisdiction over Plaintiffs.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

Answer: Plaintiffs' admit that for the purpose of this litigation only, venue is proper in this District.

Patent-In-Suit

8. On or about August 24, 2004, the United States Patent and Trademark Office issued U.S. Patent No. 6,780,881 B2 (the "'881 patent"), entitled "FREEZE-DRIED PANTOPRAZOLE PREPARATION AND PANTOPRAZOLE INJECTION," to Rudolph Linder and Rango Dietrich.

Answer: Admitted.

9. Plaintiffs purport and claim to own, and/or have the right to enforce, the '881 patent.

Answer: Plaintiffs admit that they either own or have the right to enforce the '881 patent.

10. On or about February 7, 2008, Plaintiffs filed this action against Apotex Inc. alleging infringement of the '881 patent under 35 U.S.C. § 271(e)(2)(A).

Answer: Admitted.

COUNT I
(Declaration of Non-Infringement of the ‘881 Patent)

11. Apotex Inc. incorporates by reference the allegations of Paragraphs 1-10.

Answer: In response to the allegations contained in paragraph 11 of the counterclaims Plaintiffs reallege each reply to each allegation of paragraphs 1-10 of the Counterclaims as if set forth specifically here verbatim.

12. A present, genuine, and justiciable controversy exists between Plaintiffs and Apotex Inc. regarding, *inter alia*, non-infringement of the ‘881 patent.

Answer: Plaintiffs admit that a present, genuine, and justiciable controversy exists only to the extent Apotex continues to deny the infringement of the claims of the ‘881 patent.

13. The manufacture, use, sale, offer for sale or importation of the Pantoprazole Sodium Injectable, I.V. 40 mg that is the subject of Apotex Inc’s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the ‘881 patent.

Answer: Denied.

14. Apotex Inc. is entitled to a declaration that the manufacture, use, sale, offer for sale or importation of the Pantoprazole Sodium Injectable, I.V. 40 mg, that is the subject of Apotex Inc’s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claim of the ‘881 patent.

Answer: Denied.

COUNT II
(Declaration of Invalidity of the ‘881 Patent)

15. Apotex incorporates by reference the allegations of Paragraphs 1-14.

Answer: In response to the allegations contained in paragraph 15 of the counterclaims Plaintiffs reallege each reply to each allegation of paragraphs 1-14 of the Counterclaims as if set forth specifically here verbatim.

16. A present, genuine, and justiciable controversy exists between Plaintiffs and Apotex Inc. regarding, *inter alia*, the validity of the claims of the '881 patent.

Answer: Plaintiffs admit that a present, genuine, and justiciable controversy exists only to the extent Apotex continues to deny the validity of the claims of the '881 patent.

17. The claims of the '881 patent are invalid for failure to satisfy one or more conditions for patentability under Title 35 of the United States Patent Code.

Answer: Denied.

18. Apotex Inc. is entitled to a declaration that the claims of the '881 patent are invalid.

Answer: Denied.

Responding to Apotex's Request for Relief, Plaintiffs deny that Apotex is entitled to any relief whatsoever, whether as requested or otherwise. Plaintiffs respectfully request judgment in their favor and against Apotex on Counts I and II of Apotex's Counterclaims, including costs, fees, and whatever other relief the Court deems appropriate.

Dated: April 24, 2008

/s/ James B. Coughlan

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